

# Greenberg Traurig



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August 6, 2004

Office of International Corporate Finance  
Securities and Exchange Commission  
Stop 3-2  
450 Fifth Street, N.W.  
Washington, D.C. 20549



Re: Australian Cancer Technology Limited. (the "Issuer")  
File Number ~~82-34287~~

To Whom it May Concern:

82-34767

SUPPL

On behalf of the Issuer, we enclose for submission the following reports as filed in Australia:

1. Announcement to the ASX dated April 13, 2004;
2. Announcement to the ASX, dated April 19, 2004 ;
3. Announcement to the ASX, dated April 30, 2004;.
4. Announcement to the ASX, dated May 20, 2004;
5. Announcement to the ASX, dated June 22, 2004;
6. Announcement to the ASX, dated June 23, 2004;
7. Shareholder newsletter, dated July, 2004;
8. Announcement to the ASX, dated June 28, 2004;
9. Announcement to the ASX, dated July 1, 2004;
10. Announcement to the ASX, dated July 5, 2004;
11. Announcement to the ASX, dated July 6, 2004; and
12. Announcement to the ASX, dated July 13, 2004;

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Securities and Exchange Commission  
August 6, 2004  
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The information is being submitted to the Securities and Exchange Commission with respect to the Issuer's obligations pursuant to Rule 12g3-2(b), and with the understanding that, in accordance with the terms of paragraph (b)(4) of Rule 12g3-2(b), such information and documents will not be deemed "filed" with the Commission, or otherwise subject to the liabilities of Section 18 of the Exchange Act. Kindly acknowledge receipt of the enclosed by stamping and returning the enclosed copy of this letter in the pre-addressed, stamped envelope provided for your convenience.

Very truly yours,

Ross Kaufman

File No. 82-34287

australian  
cancer  
technology 

ASX/MEDIA RELEASE

13 April 2004

## **PHASE II PENTRIX™ TRIAL TO COMMENCE**

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The Phase II clinical trial of Australian Cancer Technology's ("AustCancer") (ASX:ACU) Pentrix™ anti-idiotypic cancer vaccine is about to commence following the arrival of the Pentrix vaccine from San Diego, late last week.

The formulated Pentrix™ vaccine has been delivered to the Melbourne-based trial centres from the US manufacturer, and recruitment of patients for the trial will now commence.

The Phase II trial will be conducted by Cancer Trials Australia at three sites - The Austin Hospital, Royal Melbourne Hospital and Peter MacCallum Cancer Centre. A total of 40 patients with hormone refractory prostate cancer will be enrolled at the sites to evaluate the clinical efficacy of Pentrix™ and confirm the safety of the new vaccine formulation.

The vaccine was manufactured at Prima Pharm Inc, San Diego, an ISO certified (BSI) and FDA inspected cGMP manufacturer of drugs, devices, cosmetics and diagnostic products. Multiple Peptide Systems (MPS) in San Diego, California manufactured the active pharmaceutical ingredients.

-ENDS-

### **PLEASE DIRECT ENQUIRIES TO:**

Paul Hopper  
Managing Director  
Australian Cancer Technology Ltd  
Phone: +61-2 9252 6899  
Mob: +61-407 118 366

Anne Micic (for clinical trial details)  
Kendle Pty Ltd  
Phone: +61 3 9564 8090

Mike Feehan  
Monsoon Communications  
Phone: +61 3 9620 3333  
Mob: +61 412 537 533

**[www.austcancer.com.au](http://www.austcancer.com.au)**

**[www.cancertrialsaustralia.com](http://www.cancertrialsaustralia.com)**

### **About Pentrix™**

Pentrix™ works by inducing the production of a cascade of antibodies, which trigger an immune response against tumour cells with a mutated p53 gene. Mutated p53 occurs in up to 50% of all cancer patients. Therefore, Pentrix™ differs from other vaccines currently in development in that it can be used in up to 50% of all cancer patients and across a broad spectrum of cancer types. Most other development vaccines are designed to treat one specific type, or sub-type, of cancer and many use a patient's own cells and are therefore individually tailored for each patient resulting in regulatory as well as cost and time efficiency issues. Pentrix™ has no such issues making it a potential blockbuster product of interest to global pharmaceutical companies when compared to most competing technologies. The potential market for the vaccine has been estimated at US\$2 billion per annum.

**AUSTRALIAN CANCER TECHNOLOGY - ASX RELEASE**

Pentrix Phase II Trial to commence April 2004

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**About Australian Cancer Technology**

Australian Cancer Technology is a broadly based international oncology company developing a portfolio of high quality oncology-related projects that are at various stages of commercialisation. Cash generating businesses will provide the funds to exploit the potential of its leading products and to introduce promising pre-clinical and Phase I projects into the development pipeline. Its leading edge Pentrix™ anti-cancer vaccine successfully completed Phase I and Phase Ib/IIa trials at St. Vincent's Hospital Sydney and will soon undergo a comprehensive Phase II trial with prostate cancer patients in Melbourne. AustCancer's US subsidiary, **revisys™**, is launching a range of nutritional supplements designed by leading US scientists for people with special needs, including those undergoing cancer treatment. That business is expected to be cash positive in year one. The company is also broadening its cancer therapeutic development pipeline, which currently includes a new oncology drug (CHK1 Kinase Inhibitor) to optimise the efficacy of chemotherapy and radiotherapy.

ASX/MEDIA RELEASE  
19 April 2004

## US Oncology Center to Offer AustCancer's revisys™ Supplements

Through its US subsidiary ACT (USA), Australian Cancer Technology ("AustCancer" ASX:ACU) announced that its full range of **revisys**™ specialty nutritional supplements will be available at the new Center for Integrative Health, founded by Dr. D. Barry Boyd at Greenwich Hospital – Yale Health. This new facility anticipates serving more than 1000 patients annually.

The integrated, multi-level **revisys**™ products are designed to meet the complex nutritional needs that accompany aging or chronic health issues, such as for patients undergoing cancer treatment. ACT (USA) will launch **revisys**™ this month and opened its U.S. headquarters in Rochester, New York late last year.

ACT (USA) CEO, Dr Mary Maida welcomed the tie-up with the Center for Integrative Health. "This deal offers a significant opportunity to be a part of a team of medical professionals and top physicians dedicated to integrative medicine," she said.

A member of the Yale New Haven Health System, Greenwich Hospital is a community teaching hospital affiliated with the Yale University School of Medicine and representing all medical specialties. To meet the needs of the surrounding communities, the hospital has expanded services and developed new programs. The new Center for Integrative Health, will be a unique facility incorporating health and wellness initiatives as well as educational outlets for patients to learn more about improving and maintaining health.

ACT's Dr Maida said that the mission of **revisys**™ is to become the leading choice of medical professionals for scientifically credible, high quality nutritional supplements. "The U.S. offers an \$18.7 billion nutritional supplement market that is expected to grow to five times its current size by 2010. In the U.S., more than 60% of doctors are referring patients for services that are complementary to, and seamlessly integrate with mainstream medical therapies," she said.

ACT announced in February that it had appointed Strong Value Group, a leading healthcare marketing group in the United States, to distribute the **revisys**™ range nationally in a non-exclusive agreement expected to generate sales in excess of US\$1 million in its first full year of operation.

AustCancer is developing a portfolio of high quality oncology-related projects that are at various stages of commercialisation. Cash generating businesses such as **revisys**™ will provide the funds to exploit the potential of the company's leading product, the Phase II Pentrix™ vaccine, and to introduce promising pre-clinical and Phase I projects into the development pipeline. The **revisys**™ business is expected to be cash positive in its first year of operation.

ENDS

**PLEASE DIRECT ENQUIRIES TO:**

Paul Hopper  
Managing Director  
Australian Cancer Technology  
Tel: +61 2 9252 6899  
Fax: + 61 2 9252 6877  
Cell: +61 407 118 366  
[paulhopper@austcancer.com.au](mailto:paulhopper@austcancer.com.au)

Mike Feehan  
Monsoon Communications Pty Ltd  
Phone: +61 3 9620 3333

Dr Mary Maida  
General Manager  
ACT (USA), INC.  
Phone +1 585-419-9710  
Fax: +1 585-419-9715

**About Australian Cancer Technology**

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**[www.austcancer.com.au](http://www.austcancer.com.au)**  
**[www.revisyshealth.com](http://www.revisyshealth.com)**

## **PHASE II CANCER VACCINE TRIAL UNDERWAY**

The Phase II clinical trial of Australian Cancer Technology's ("AustCancer") (ASX:ACU) Pentrys™ (formerly called Pentrix), an anti-idiotypic cancer vaccine, officially commenced on 28 April with the vaccination of the first patient at Melbourne's Austin Hospital.

The study is evaluating a new vaccine for men with hormone refractory prostate cancer and is being conducted by Cancer Trials Australia at three sites in Melbourne: Austin Hospital, Royal Melbourne Hospital and Peter MacCallum Cancer Centre. A total of 40 patients will be enrolled.

-ENDS-

### **PLEASE DIRECT ENQUIRIES TO:**

Paul Hopper  
Managing Director  
Australian Cancer Technology Ltd  
Phone: +61-2 9252 6899  
Mob: +61-407 118 366

Assoc. Prof Mark Rosenthal (Trial-related queries)  
Clinical Trials Australia  
Phone: +61 3 6 9342 7560

Mike Feehan  
Monsoon Communications  
Phone: +61 3 9620 3333  
Mob: +61 412 537 533

### **About Pentrys™**

Pentrys™ works by inducing the production of a cascade of antibodies, which trigger an immune response against tumour cells with a mutated p53 gene. Mutated p53 occurs in up to 50% of all cancer patients. Therefore, Pentrys™ differs from other vaccines currently in development in that it can be used in up to 50% of all cancer patients and across a broad spectrum of cancer types. Most other development vaccines are designed to treat one specific type, or sub-type, of cancer and many use a patient's own cells and are therefore individually tailored for each patient resulting in regulatory as well as cost and time efficiency issues. Pentrys™ has no such issues making it a potential blockbuster product of interest to global pharmaceutical companies when compared to most competing technologies. The potential market for the vaccine has been estimated at US\$2 billion per annum.

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## **AustCancer to Acquire U.S. Vaccine Developer**

**US\$5.0 million share offer for immune enhancer technology**  
**Lead Product GP1-0100, used in three Phase I clinical trials at major U.S.**  
**centres, including Memorial Sloan-Kettering Cancer Center in New York**  
**US\$12.0 million invested in technology to date**  
**Current corporate alliances include Pfizer and Endocyte**  
**Potential synergy with AustCancer's Pentrys<sup>TM</sup> vaccine**

The Board of Australian Cancer Technology ("AustCancer") (ASX:ACU) announced today that it had signed an agreement to acquire, through its wholly-owned U.S. subsidiary Adjuvantys Inc., the business of Galenica Pharmaceuticals Inc., a private U.S. biopharmaceutical company, for US\$5.0 million in a largely scrip offer.

Approximately US\$12.0 million has been invested in the development of Galenica's proprietary technology which comprises three families of semi-synthetic immune enhancers, or adjuvants, used to stimulate the immune system. Employed as stand-alone therapeutics, or as an essential component in vaccines, these compounds have been or are currently being used in cancer vaccines in two Phase I and one Phase I/II clinical trials at leading cancer centres in the U.S.

Galenica also has a licensing agreement with Pfizer Animal Health for a series of animal vaccines in development which will use Galenica's adjuvant, and with Endocyte for a novel active immune therapy for kidney cancer. The first milestone payment pursuant to the Pfizer agreement is expected in 2005.

Pfizer Holdings Europe, an affiliate of Pfizer Inc., and SuperGen are both shareholders in Galenica.

AustCancer managing director Paul Hopper described this transaction as a "business making" deal for the company. "We have been working aggressively on expanding our portfolio of developmental drugs. Galenica brings us exclusive rights to a novel technology with considerable potential and two products candidates already in the clinic. Galenica's patent estate includes five granted patents and one pending" he said.

"Also, Galenica's technology platform is synergistic with what AustCancer is already doing – immune enhancers are critically important in vaccines and the development of vaccines is one of our core businesses," said Mr. Hopper.

Galenica's founder and internationally recognized vaccinologist Dr. Dante Marciani welcomed the proposed acquisition. "AustCancer and Galenica both have promising development programs in the area of cancer vaccines. The combined entity will commercially exploit this strong technology platform with current and new strategic partners, and continue the ongoing development of a number of novel vaccines in the U.S. and Europe," said Dr. Marciani.

As part of the acquisition, Dr. Marciani will join AustCancer and continue to run the business.

AustCancer sees its leading edge anti-idiotypic cancer vaccine Pentrys<sup>TM</sup> as an obvious candidate for evaluation with the Galenica adjuvants. Pentrys<sup>TM</sup> is in a Phase IIb clinical trial on prostate cancer patients at three leading Melbourne hospitals.

Under the terms of the acquisition, AustCancer will issue 1,955,758 ordinary shares of AustCancer stock at 48 cents per share and pay US\$350,000 in cash upon closing; an additional US\$3.0 million will be paid in 12 months time in AustCancer stock or cash at AustCancer's option; and a final US\$1.0 million payment in AustCancer stock or cash at



20 May 2004

AustCancer's option will be made in 24 months time and will be subject to specific performance milestones. The acquisition is subject to final due diligence by both parties, approval by AustCancer shareholders and execution of definitive purchase agreements. A General Meeting of AustCancer Shareholders will be held in mid July, to ratify the acquisition.

BIO-IB, LLC, a New York based boutique investment bank, acted as financial advisor to AustCancer for this transaction.

ENDS

Please direct enquiries to:

**Australian Cancer Technology Limited**

Paul Hopper  
Managing Director,  
Level 36, Suite 4, 88 Phillip Street  
SYDNEY New South Wales, Australia 2000  
Phone: +61 2 9252 6899  
Cell: +61 407 118 366  
[paulhopper@austcancer.com.au](mailto:paulhopper@austcancer.com.au)

**Galenica Pharmaceuticals, Inc**

Dr Dante Marciani, ScD., Ph.D.  
Chief Executive Officer  
2800 Milan Court  
Suite 118, Birmingham ALABAMA 35211  
Phone: +1-205-969-5829  
Cell: +1-205-821-3177  
[dmarciani@galenicapharma.com](mailto:dmarciani@galenicapharma.com)

**BIO-IB, LLC**

Mr. Ashish Sanghrajka  
Managing Director  
Chrysler Center  
666 Third Avenue, 16th Floor  
New York, NY 10009  
Phone: +1 212 697 2007  
Cell: +1 917 446 2130  
[ashish@bio-ib.com](mailto:ashish@bio-ib.com)

**Galenica Fact Sheet**

Founded in 1996, and privately financed, Galenica recognized that multiple components are needed to develop effective vaccines. The company focuses on developing proprietary technology in immune enhancers, carriers and antigens - new therapeutic agents aimed at enabling physicians to modulate the body's immune system by providing protection and treatment against an array of diseases.

Galenica has assembled a strong technology base in medicinal chemistry and immunology for use in the expanding field of vaccines for cancer and infectious diseases.

GP1-0100, Galenica's lead immune enhancer, is currently being evaluated in two clinical trials. A Phase I trial at the University of Alabama at Birmingham (UAB) Comprehensive Cancer Center is evaluating a HER-2 vaccine containing GPI-0100 and a novel antigen for

the treatment of breast cancer patients that have developed resistance against the drug Herceptin™. A Phase I trial, conducted by Endocyte, a Galenica licensee, at Baylor University Texas, is evaluating a GPI-0100 and folate antigen complex for renal cancer.

A Phase I/II trial at the prestigious Memorial Sloan-Kettering Cancer Center in New York was conducted in 2003 to evaluate a GP1-0100/antigen complex to prevent recurrence of prostate cancer in patients that have responded to the initial treatment.

Galenica also intends to commence a Phase I clinical trial using a CEA vaccine for colorectal cancer, at the UAB Comprehensive Cancer Center in 2005.

An immune enhancer or adjuvant is a critical vaccine component that is required to stimulate a protective or therapeutically effective immune response against cancer cells or infectious agents. Galenica's GPI-0100 series are safe semi-synthetic derivatives from certain natural saponins which have the capability of stimulating Th 1 immunity with production of antigen-specific cytotoxic T cells (CTL) that will seek out and destroy cells carrying abnormal markers such as viral or tumor antigens. Pre-clinical work has shown that the GPI-0100 derivatives can also be used as stand-alone drugs in cancer immunotherapy.

(more)

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For further information on AustCancer visit [www.austcancer.com.au](http://www.austcancer.com.au).

ASX/Media Release  
22 June 2004

## **AustCancer's Galenica Signs Materials Transfer Agreement With Memorial Sloan-Kettering in New York**

Australian Cancer Technology ("AustCancer") (ASX:ACU) announced today that its soon to be acquired US business, Galenica Pharmaceuticals, had signed an agreement with the prestigious Memorial Sloan-Kettering Cancer Center for the use of Galenica's lead product, the GPI-0100 adjuvant, in a series of clinical trials.

Over the next year, Memorial Sloan-Kettering intends to use GPI-0100 in conjunction with specific vaccine antigens in a several clinical trials in patients with melanoma, sarcoma, neuroblastoma, small cell lung cancer and cancers of the breast or ovary. If consistent antibody responses are demonstrated in these small trials, the use of the vaccine adjuvant (GPI0100) will be expanded into Phase II trials in these settings (30 to 100 patients). In addition to these clinical trials, Sloan-Kettering will be conducting a series of preclinical studies looking for approaches that further optimize the adjuvant effect of GPI-0100.

Memorial Sloan-Kettering Cancer Center in New York is one of the largest and most highly regarded cancer treatment and research organisations in the world. With origins dating back over a hundred years, the center now employs over 8,000 people. Memorial Hospital treats nearly 20,000 in-patients and has nearly 400,000 outpatient visits annually.

"This is a huge boost to our objective of broadening our range of developmental cancer therapeutics," AustCancer managing director Paul Hopper said. "Prior to the Galenica acquisition our only product in the clinic was the promising Pentrys™ vaccine, which is in a Phase IIb prostate cancer trial in Melbourne. With this development, we will be involved in 10 or more clinical trials and we will be working with some of the world's best cancer researchers to prove and improve the performance of the Galenica adjuvants."

The decision by Memorial Sloan-Kettering to work with Galenica products follows a Phase I/II trial at the Center in 2003, which evaluated a GP1-0100/antigen complex in patients with prostate cancer.

AustCancer announced the US\$5 million (mostly scrip) acquisition of Galenica Pharmaceuticals last month and the deal is expected to be finalised in July. Galenica had invested around US\$12 million in the development of its proprietary technology, which comprises three families of semi-synthetic immune enhancers or adjuvants used to stimulate the immune system. The products are used as either stand-alone therapeutics or as is the case with the Sloan-Kettering trials, as an essential component in vaccines. A General Meeting of AustCancer shareholders will be held next month to ratify the acquisition.

ENDS

Please direct enquiries to:

**Australian Cancer Technology Limited**  
Paul Hopper  
Managing Director,  
Level 36, Suite 4, 88 Phillip Street  
SYDNEY New South Wales, Australia 2000  
Phone: +61 2 9252 6899  
Cell: +61 407 118 366  
[paulhopper@austcancer.com.au](mailto:paulhopper@austcancer.com.au)

**Galenica Pharmaceuticals, Inc**  
Dr Dante Marciani, ScD., Ph.D.  
Chief Executive Officer  
2800 Milan Court  
Suite 118, Birmingham ALABAMA 35211  
Phone: +1-205-969-5829  
Cell: +1-205-821-3177  
[dmarciani@galenicapharma.com](mailto:dmarciani@galenicapharma.com)

### **About Galenica**

Founded in 1996, and privately financed, Galenica recognized that multiple components are needed to develop effective vaccines. The company focuses on developing proprietary technology in immune enhancers, carriers and antigens - new therapeutic agents aimed at enabling physicians to modulate the body's immune system by providing protection and treatment against an array of diseases.

Galenica has assembled a strong technology base in medicinal chemistry and immunology for use in the expanding field of vaccines for cancer and infectious diseases. GP1-0100, Galenica's lead immune enhancer, is currently being evaluated in two clinical trials. A Phase I trial at the University of Alabama at Birmingham (UAB) Comprehensive Cancer Center is evaluating a HER-2 vaccine containing GPI-0100 and a novel antigen for the treatment of breast cancer patients that have developed resistance against the drug Herceptin™. A Phase I trial, conducted by Endocyte, a Galenica licensee, at Baylor University Texas, is evaluating a GPI-0100 and folate antigen complex for renal cancer. A Phase I/II trial at the prestigious Memorial Sloan-Kettering Cancer Center in New York was conducted in 2003 to evaluate a GP1-0100/antigen complex to prevent recurrence of prostate cancer in patients that have responded to the initial treatment. Galenica also intends to commence a Phase I clinical trial using a CEA vaccine for colorectal cancer, at the UAB Comprehensive Cancer Center in 2005.

An immune enhancer or adjuvant is a critical vaccine component that is required to stimulate a protective or therapeutically effective immune response against cancer cells or infectious agents. Galenica's GPI-0100 series are safe semi-synthetic derivatives from certain natural saponins which have the capability of stimulating Th 1 immunity with production of antigen-specific cytotoxic T cells (CTL) that will seek out and destroy cells carrying abnormal markers such as viral or tumor antigens. Pre-clinical work has shown that the GPI-0100 derivatives can also be used as stand-alone drugs in cancer immunotherapy.

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**For further information on AustCancer visit [www.austcancer.com.au](http://www.austcancer.com.au).**

File No. 82-34287



ASX/Media Release  
23 June 2004

## Galenica Acquisition Finalised

Australian Cancer Technology ("AustCancer") (ASX:ACU) chairman Roger Aston and managing director Paul Hopper announced from New York today that due diligence on the proposed US\$5 million Galenica Pharmaceuticals acquisition was completed satisfactorily and final documentation signed today. The acquisition is now subject only to the approval of AustCancer shareholders at an extraordinary general meeting on July 19th.

Galenica's proprietary technology comprises three families of semi-synthetic immune enhancers, or adjuvants, which are used to stimulate the immune system. Employed as stand-alone therapeutics, or as an essential component in vaccines, these compounds have been or are currently being used in cancer vaccines in two Phase I and one Phase I/II clinical trials at leading cancer centres in the U.S.

Subject to shareholder approval at the July EGM, Galenica will formally become part of AustCancer. Galenica founder Dr Dante Marciani will join AustCancer and continue to run the business.

ENDS

Please direct enquiries to:

**Australian Cancer Technology Limited**  
Paul Hopper  
Managing Director,  
Level 36, Suite 4, 88 Phillip Street  
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Phone: +61 2 9252 6899  
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For further information on AustCancer visit [www.austcancer.com.au](http://www.austcancer.com.au).

ASX/MEDIA RELEASE

26 July 2004

## **AustCancer Appoints Singapore Distributor for revisys™ Supplements**

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Australian Cancer Technology Limited ("AustCancer") (ASX: ACU) today announced that its US subsidiary, ACT (USA) Inc, has appointed Hengzi Technology Investment Pte Ltd as exclusive distributor of the revisys™ range of nutritional supplements in Singapore. This is the first distribution deal for the products in a market outside the United States.

Hengzi Technology is a specialist supplier to health professionals in the Asia Pacific region where it markets and distributes a range of medical devices and pharmaceutical products on behalf of a number of prominent international healthcare companies. The company is in partnership with VRI BioMedical, an Australian Biotechnology company, in establishing its Gastrointestinal Health Products in S.E. Asia & South Asia.

Hengzi Technology director, Ms Lim Linbert, sees the revisys™ range satisfying a growing need in the Singapore market for premium nutritional supplements. "Most western medicine patients in Singapore would also seek complementary medicines for their conditions. There is an increasing call for complementary products that are backed by sound medical science," Ms Lim said.

Revisys™ is an integrated, multi-level nutrient system that provides support for four levels of health and nutritional needs, from general well-being to condition-specific supplementation. It is particularly designed for patients facing unique nutritional requirements due to extenuating health issues. Developed by leading medical scientists and launched in the United States in February this year, revisys aims to become the leading choice of medical professionals for scientifically credible, high quality nutritional supplements.

AustCancer managing director Paul Hopper said, "We've made good early progress in penetrating the United States market with revisys™ and we are now ready to start developing a position in other markets. Singapore intrinsically appeals as a strong potential market for us and if it meets our expectations, expansion into other Asian countries would be a logical next step."

The revisys™ products will be launched into the Singapore market in November this year. The products' developers, the prominent US medical scientists Professor David Felten and Professor Barry Boyd, will introduce revisys™ in a series of presentations to Singapore oncologists and other health professionals. The critical success factor is to convince Medical practitioners in Singapore that revisys™ products and value proposition are superior.

Product for the Singapore market will be manufactured by ACT (USA) in Australia, where plans are also underway to launch revisys™ by December 2004

ACT (USA) has estimated that total (domestic and export) sales of revisys™ will be of the order of US\$8-10 million pa by 2006.

-ENDS-

**AUSTRALIAN CANCER TECHNOLOGY - ASX RELEASE**

AustCancer Appoints Singapore Distributor for revisys™ Supplements

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**PLEASE DIRECT ENQUIRIES TO:**

Paul Hopper  
Managing Director  
Australian Cancer Technology  
Tel: +61 2 9252 6899  
Fax: + 61 2 9252 6877  
Cell: +61 407 118 366  
[paulhopper@austcancer.com.au](mailto:paulhopper@austcancer.com.au) <<mailto:paulhopper@austcancer.com.au>>

Dr Mary Maida  
General Manager  
ACT (USA), INC.  
Phone +1 585-419-9710  
Fax: +1 585-419-9715

**Australian Cancer Technology**

Australian Cancer Technology is a broadly based international oncology company developing a portfolio of high quality oncology-related projects that are at various stages of commercialisation. Cash generating businesses will provide the funds to exploit the potential of its leading products and to introduce promising pre-clinical and Phase I projects into the development pipeline. Its leading edge Pentrys anti-cancer vaccine successfully completed Phase I and Phase I/IIa trials at St. Vincent's Hospital Sydney and is undergoing a comprehensive Phase IIb trial with prostate cancer patients at three leading Melbourne institutions. Its US subsidiary, revisys, is launching a range of nutritional supplements designed by leading US scientists for people with special needs, including those undergoing cancer treatment. The company is also broadening its cancer therapeutic development pipeline and has recently announced the acquisition of US based Galenica Pharmaceuticals, whose immune enhancing products are being used in three Phase I cancer vaccine trials and will be used in a number of other forthcoming clinical trials in association with Memorial Sloan Kettering Cancer Centre in New York and The University of Alabama. AustCancer has completed a Level 1 ADR program on NASDAQ (AUCJY).

[www.austcancer.com.au](http://www.austcancer.com.au) <<http://www.austcancer.com.au/>>  
[www.revisyshealth.com](http://www.revisyshealth.com) <<http://www.revisyshealth.com/>>



2004 HOLDER

# newsletter

JULY|04

File No. 82-34287

## Message from the Managing Director

australian cancer technology



It is only three months since our last newsletter, but there have been a number of very significant developments for our company in that time.

The biggest of these recent developments was the announcement of the acquisition of the US based Galenica Pharmaceuticals business. At the time of the announcement, I described this acquisition, which is subject to shareholder approval, as a "business making" deal for the company. Galenica brings us exclusive rights to a new technology stream with considerable potential and two products already in the clinic.

The Galenica acquisition fits perfectly with our objective of building an international portfolio of quality oncology drugs which are advanced to the human trial stages of development. Since we have become better known in international, particularly US, cancer drug research circles, we have had a number of development projects offered to us, but have steadfastly held to our strategic principles and rejected those that were either not sufficiently advanced or did not have the potential we are after.

We have exceeded our targets by a considerable margin in what has been a particularly busy last few months. I am pleased to report substantial progress on all six of the strategic priorities for 2004 that we highlighted in our March newsletter.

**1. Commence Phase IIb Pentrys™ (formerly called Pentrix) trial:** The Phase IIb trial formally commenced in April with the vaccination of the first of 40 prostate cancer patients. The start of the trial attracted national media attention.

**2. Rapidly develop US revisys™ market:** The first supplies of the revisys™ specialised medical nutritionals were released onto the US market in May. We also announced that a new oncology center at Greenwich Hospital Yale would be carrying the full

revisys™ range and that some substantial distribution agreements had been signed.

**3. Expand drug development pipeline:** The Galenica acquisition expands our portfolio of cancer therapeutics in clinical trials from one to four. This number will increase further as a result of a subsequent announcement that Galenica products will be used in trials in New York's Memorial Sloan-Kettering Cancer Center.

**4. Strengthen the Board and team of scientific advisers:** We have expanded our Board with the appointment of medical practitioner and international healthcare businessman, Dr Richard Opara. Through the Galenica deals, we now also have access to the technical expertise of international vaccinologist and Galenica founder Dr Dante Marciani and Prof. Phil Livingston of New York's prestigious Memorial Sloan-Kettering Cancer Centre. Prof Livingston is the Professor of Medicine of Cornell University's Weill Graduate School of Medical Sciences at Memorial Sloan-Kettering, one of the country's top facilities for cancer research and treatment. We also strengthened our managerial team with the appointment of former Cochlear executive, Tom Milicevic, as CFO.

**5. Position the company to maximise its appeal to investors in local and international capital markets:** In March we raised \$3 million in a successful capital raising to institutional and sophisticated investors.

**6. NASDAQ Level 1 ADR listing:** This program was officially completed on 23 of June when ACU's shares were quoted on the OTC Bulletin Board, trading under the ticker symbol AUCJY.

Around the middle of last year, the Board first committed to the mission of establishing AustCancer as a broad-based oncology business of international standing. At that time, we had a market capitalization of \$9m and one main product in Pentrys™. Less than a year later, our market capitalization has increased by a factor of five and the number of cancer drugs



## US Acquisition a "Business Making Deal" for AustCancer

The AustCancer Board recently announced that it had signed an agreement to acquire the US based biopharmaceutical business, Galenica Pharmaceuticals Inc. for US\$5.0 million in a largely scrip offer.

Established in 1996, Galenica has invested around US\$12 million in the development of its proprietary

technology which comprises different families of semi-synthetic saponin analogs, or immuno potentiators or adjuvants, for use in vaccines to stimulate the immune system. Galenica's

adjuvants are an essential component in a vaccine, and are currently being used in cancer vaccines in two Phase I clinical trials at leading US cancer centers.

The company also has a commercial contract with Pfizer Animal Health for a series of animal vaccines using Galenica's adjuvant, and with Endocyte for a novel vaccine for kidney cancer. The first milestone payments from the Pfizer contract are expected in 2005. Pfizer and another large pharmaceutical company, SuperGen, are both small shareholders in Galenica.

GPI-0100, Galenica's lead adjuvant, has been evaluated in three Phase I clinical trials. A trial at the University of Alabama Birmingham Cancer Centre is evaluating the GPI-0100 adjuvant in conjunction with a novel antigen directed against HER-2, the target of Genentech's breast cancer drug Herceptin. A second trial at the prestigious Memorial Sloan-Kettering Cancer Centre in New York, evaluated a GPI-0100/antigen complex to prevent recurrence of prostate cancer in patients that have responded to the initial treatment. An ongoing trial for a kidney cancer vaccine is being

conducted at Baylor University, Texas, by a Galenica licensee, Endocyte, Inc., using GP1-0100. Galenica also has plans to commence a Phase 1 clinical trial using a CEA vaccine for breast cancer, at The University of Alabama Birmingham Cancer Centre in 2005.

AustCancer managing director Paul Hopper described the acquisition as a "business making" deal for the company. "We have been aggressively working on expanding our portfolio of developmental drugs. Galenica brings us exclusive rights to a novel technology with considerable potential and three products already in the clinic. Galenica's patent estate includes five granted patents and one pending" he said.

AustCancer sees its leading edge anti-idiotype cancer vaccine Pentrys™ as an obvious candidate for evaluation with the Galenica adjuvants. Pentrys™ is in a Phase IIb clinical trial on prostate cancer patients at three leading Melbourne hospitals.

Under the terms of the acquisition, AustCancer will pay US\$1.0m in AustCancer stock upon closing, a further US\$3.0m in AustCancer stock in 12 months time, and a final US\$1.0m in 24 months time subject to Galenica meeting specific performance milestones. The acquisition is subject to approval by AustCancer shareholders and a general meeting of shareholders will be held on 19th July to ratify the acquisition.

Galenica is currently based in Alabama but will soon be moving to the US west coast. Galenica founder and current chief executive Dr Dante Marciani will join AustCancer and continue to run the business.

For further information on Galenica visit:

[www.galenicapharma.com](http://www.galenicapharma.com)

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## Pentrys™ Prostate Cancer Trial Underway

The Phase IIb clinical trial of our leading drug candidate Pentrys™ (formerly called Pentrix), an anti-idiotypic cancer vaccine, officially commenced on 28 April with the vaccination of the first patient at Melbourne's Austin Hospital.

The study is evaluating the vaccine for men with prostate cancer not responding to hormone treatment. The trial is being conducted by Cancer Trials Australia at three sites in Melbourne - Austin Hospital, Royal Melbourne Hospital and Peter MacCallum Cancer Centre. A total of 40 patients will be enrolled.

The commencement of the trial attracted national television news coverage.

## Profile – Dr Dante Marciani



Dr Marciani, the founder and current chairman and chief scientific officer of Galenica, will join AustCancer and continue to run the Galenica business which will be owned by ACU's wholly owned US subsidiary, Adjuvantys Inc., when the acquisition is complete.

Prior to founding Galenica, Dr. Marciani was at Cambridge Biotech Corporation (now a division of Antigenics, Inc.) where his last position was Senior Vice President & Chief Scientific Officer. Before that, his roles included Research Director at Bethesda Research Laboratories, Inc. and an investigator at the National Cancer Institute at the NIH. He received his B.S. in Biological Sciences from the University of San Marcos, Lima, Peru, a Sc.D. from the same University, and a Ph.D. in Chemistry from the University of Colorado.

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## Cochlear Finance Executive Joins AustCancer as CFO



Former Cochlear executive, Tom Milicevic, recently joined AustCancer to take up the positions of Chief Financial Officer and Company Secretary.

Tom had been Group Chief Accountant with Cochlear, having worked with the leading medical device company for the past four years. He had responsibility for consolidation of forecasts, budgets, strategic plans and financial reports for the multi-national Cochlear group.

Tom is located in the company's Sydney head office.

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## Galenica Signs Clinical Trial Agreements with Memorial Sloan-Kettering

Barely a month after the announcement of its acquisition by AustCancer, Galenica signed two agreements with the prestigious Memorial Sloan-Kettering Cancer Center for the use of its lead product, the GPI-0100 adjuvant, in a series of clinical trials.

Over the next year, Memorial Sloan-Kettering intends to use GPI-0100 in conjunction with specific vaccine antigens in several clinical trials in patients with melanoma, sarcoma, neuroblastoma, small cell lung cancer and cancers of the breast or ovary. If consistent antibody responses are demonstrated in these small trials, the use of the vaccine adjuvant (GPI-0100) will be expanded into Phase II trials in these settings (30 to 100 patients). In addition to these clinical trials, Sloan-Kettering will be conducting a series of preclinical studies looking for approaches that further optimise the adjuvant effect of GPI-0100.

Memorial Sloan-Kettering Cancer Center in New York is one of the largest and most highly regarded cancer treatment and research organisations in the world. With origins dating back over a hundred years, the center now employs over 8,000 people. Memorial Hospital treats nearly 20,000 in-patients and has nearly 400,000 outpatient visits annually.

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## Message from the Managing Director (cont.)

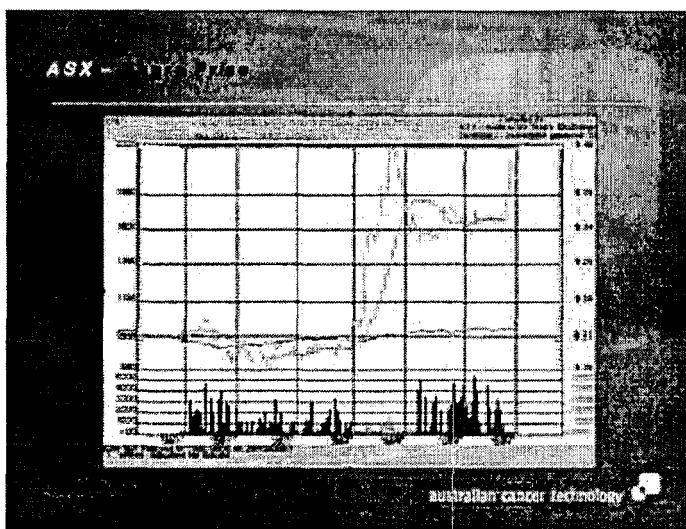
we have in clinical trials by a factor of four. We now have a new cash generating business in the US and a number of new and important relationships with significant individuals and organizations in the US and European biotechnology industry. There is a lot more to do, but we have taken some important steps towards

achieving that strategic mission for our company. The strength of our share price indicates a high level of shareholder support for the direction we are taking.

**Paul Hopper**  
Managing Director

## AustCancer one of best performing biotech stocks

Leading stockbrokers, **Citigroup Smith Barney**, has ranked AustCancer as one of the top ten (number 6) Australian biotech stocks in terms of shareholder returns in the 12 months ending March 31. In the rankings for Q1 2004, AustCancer was second overall.



AustCancer went one better in the June quarter to be ranked the best performing biotech stock by the respected industry journal **Bioshares** which said in its July 2 edition under the heading **Outperformers – ACU leads the pack**:

*The leading biotech stock for the quarter was Australian Cancer Technology, which increased by 55% and 167% over the first six months of 2004. Australian Cancer has been making progress on all fronts, broadening its business to become a diversified biotech and nutraceutical company. The company has moved its head office to Sydney and appointed an experienced CEO Paul Hopper last year. This year it has started selling its nutraceutical range of products in the US, its Pentrix vaccine has moved into Phase II (b) trials in 40 patients, and the company has acquired a US vaccine adjuvant business, Galenica Pharmaceuticals.*

A more detailed review of the company in an earlier edition of **Bioshares** has been included as an insert with this newsletter.

And this is an extract from the July 2 edition of **Southern Cross Equities Biotechnology Buzz**, edited by Stuart Roberts (stuartr@sceq.com.au):

*Australian Cancer Technology, which went from 12.5 cents to 52 cents for a 316% return in 2003/2004, has been a hit with investors for five main reasons. Chief among them has been the appeal of the company's CEO since last year, Paul 'Dennis' Hopper. The market gave a vote of confidence to Hopper in large measure because he already had a track record in building a public company, formed when he was in charge of the private hospital operator Alpha during the 1990s. Also a significant help to Austcancer was the move by the company into the development of nutraceuticals for chemotherapy patients, which to this analyst represents a promising and relatively novel business idea that will likely go places so long as distribution is managed well. Still of interest to many Austcancer followers was its Pentrix anti-p53 antibody drug, which moved into a Phase II clinical trial setting recently, suggesting that the older parts of the Austcancer story were starting to deliver the goods. And let's not forget Austcancer's Level 1 ADR programme in the US, which has likely added some liquidity to the stock, and the various other projects Hopper has brought into Austcancer, such as the Galenica vaccine adjuvants technology. The whole package has suggested a company on the move. We haven't covered Austcancer during this stunning rise to market leadership but we think that Hopper deserves congratulations for the speed with which this scientific layman has learned on the job. Moreover Pentrix in particular continues to look interesting. This is one to Watch. The lesson for investors on Austcancer: Investors tend to like a CEO that is a 'known quantity', even if he or she doesn't come out of the biotech industry. They also like a company that looks busy and has at least one business that is easy to understand.*

### Company updates by email?

If you would like to be added to our database to receive company news and updates by email, please register your email address at: [info@austcancer.com.au](mailto:info@austcancer.com.au)

Australian Cancer Technology Ltd  
Level 36 Suite 4, 88 Phillip St Sydney 2000  
Phone: (02) 9252 6899 [www.austcancer.com.au](http://www.austcancer.com.au)

## **AustCancer US ADR Program Established**

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Australian Cancer Technology ("AustCancer") (ASX:ACU) announced today that its Level One American Depositary Receipt (ADR)\* program has been declared effective by the US Securities and Exchange Commission.

Establishing the Level One ADR program is part of a broader program of accessing the US capital markets to expand AustCancer's shareholder base and strengthen the company's financial position. The Level One ADR program is an important step towards the company's previously announced objective of listing on NASDAQ. The New York based investment bank, Global Markets Capital Group, is managing the ADR and NASDAQ listing processes for AustCancer as well as assisting the company to identify strategic US merger and acquisition opportunities. The Bank of New York has been appointed as the depositary bank for the ADR program.

As a key element of its growth strategy, AustCancer is rapidly building its presence in the US market. It launched its **revisys**<sup>TM</sup> nutraceuticals into the high-end US complementary medicine market earlier this year and recently announced the US\$5 million acquisition of Galenica Pharmaceuticals, whose immune enhancing technology is being used in three Phase I clinical trials at leading cancer centers in the US.

"The awareness of AustCancer in US cancer research and treatment circles is growing steadily as a result of our expanding business activities there. We now aim to gain awareness and consequent investment interest in the world's largest capital market," AustCancer's Managing Director Paul Hopper said.

AustCancer's ADR code is ACUJY.

### **\*About ADRs (American Depositary Receipts)**

ADRs are commonly used to facilitate US investors investing in non-US companies. An ADR is created when a broker purchases the company's shares on the home stock market and delivers those to the depositary's local custodian bank, which then instructs the depositary bank to issue Depositary Receipts. Depositary Receipts may trade freely, just like any other security, in the US Over-the-Counter (OTC) market.

### **AustCancer sponsored Level One American Depositary Receipts**

AustCancer has established a sponsored Level One ADR program, which is a convenient way to access the US market. The company's Level One American Depositary Receipts will be traded in the US OTC market. The company does not have to comply with US Generally Accepted Accounting Principles (GAAP) or full Securities and Exchange Commission (SEC) disclosure. Essentially a sponsored Level One Depositary Receipt program allows companies to enjoy certain benefits of a publicly traded security in the US without changing its current reporting process.

### **NASDAQ listing of ADRs**

AustCancer plans at a later stage to register on Form 20-F with the SEC as a foreign private issuer as part of its next step of achieving the more significant Level Two ADR program. A Level Two ADR program is a US listing (with US GAAP and full SEC compliance). The listing will allow for AustCancer's ADRs to trade on the fully automated, screen based Small Cap NASDAQ market.

US brokers may deal either directly in AustCancer shares or in ADRs. Some US investors, particularly certain domestic mutual funds, are constrained from investing directly in non-US securities and the ADR programs will provide the opportunity for them to invest in ASX listed AustCancer.

ENDS

Please direct enquiries to:

#### **Australian Cancer Technology Limited   Global Markets Capital Group, LLC**

Paul Hopper  
Managing Director,  
Level 36, Suite 4, 88 Phillip Street,  
SYDNEY New South Wales, Australia 2000  
Phone: +61 (0) 407 118 366  
[paulhopper@austcancer.com.au](mailto:paulhopper@austcancer.com.au)

Mark R. Saunders, President  
405 Lexington Ave, 45<sup>th</sup> Floor,  
New York, NY, 10174.  
Phone: +1 (212) 808 9700

### **About Australian Cancer Technology**

Australian Cancer Technology is a broadly based international oncology company developing a portfolio of high quality oncology-related projects that are at various stages of commercialisation. Cash generating businesses will provide the funds to exploit the potential of its leading products and to introduce promising pre-clinical and Phase I projects into the development pipeline. Its leading edge Pentrys<sup>TM</sup> anti-cancer vaccine successfully completed Phase I and Phase I/IIa trials at St. Vincent's Hospital Sydney and is undergoing a comprehensive Phase IIb trial with prostate cancer patients at three leading Melbourne institutions. Its US subsidiary has launched a range of **revisys**<sup>TM</sup> nutritional supplements designed by leading US scientists for people with special needs, including those undergoing cancer treatment. The company is also broadening its cancer therapeutic development pipeline and has recently announced the acquisition of US based Galenica Pharmaceuticals, whose immune enhancing products are being used in several Phase I and II cancer trials.

For further information on AustCancer visit [www.austcancer.com.au](http://www.austcancer.com.au).

ASX/Media Release  
1 July 2004

### **AustCancer Product in Sloan-Kettering Leukemia Study**

Australian Cancer Technology ("AustCancer") (ASX:ACU) announced today that it has signed a second material transfer agreement with New York's Memorial Sloan-Kettering Cancer Center. This latest agreement relates to the use of GPI-0100, the lead product of its Galenica Pharmaceuticals business, in a study on the potential for vaccination for leukemias and lymphomas. It follows the recently signed agreement with the prestigious cancer center covering the use of Galenica products in pre-clinical and clinical research aimed at a wide range of other cancer types.

Memorial Sloan-Kettering Cancer Center in New York is one of the largest and most highly regarded cancer treatment and research organisations in the world. With origins dating back over a hundred years, the center now employs over 8,000 people, treats nearly 20,000 in-patients and has nearly 400,000 outpatient visits annually.

ENDS

Please direct enquiries to:

#### **Australian Cancer Technology Limited**

Paul Hopper  
Managing Director,  
Level 36, Suite 4, 88 Phillip Street  
SYDNEY New South Wales, Australia 2000  
Phone: +61 2 9252 6899  
Cell: +61 407 118 366  
[paulhopper@austcancer.com.au](mailto:paulhopper@austcancer.com.au)

#### **Galenica Pharmaceuticals, Inc**

Dr Dante Marciani, ScD., Ph.D.  
Chief Executive Officer  
2800 Milan Court  
Suite 118, Birmingham ALABAMA 35211  
Phone: +1-205-969-5829  
Cell: +1-205-821-3177  
[dmarciani@galenicapharma.com](mailto:dmarciani@galenicapharma.com)

#### **About Galenica**

Founded in 1996, and privately financed, Galenica recognized that multiple components are needed to develop effective vaccines. The company focuses on developing proprietary technology in immune enhancers, carriers and antigens - new therapeutic agents aimed at enabling physicians to modulate the body's immune system by providing protection and treatment against an array of diseases.

Galenica has assembled a strong technology base in medicinal chemistry and immunology for use in the expanding field of vaccines for cancer and infectious diseases. GP1-0100, Galenica's lead immune enhancer, is currently being evaluated in two clinical trials. A Phase I trial at the University of Alabama at Birmingham (UAB) Comprehensive Cancer Center is evaluating a HER-2 vaccine containing GPI-0100 and a novel antigen for the treatment of breast cancer patients that have developed resistance against the drug Herceptin™. A Phase I trial, conducted by Endocyte, a Galenica licensee, at Baylor University Texas, is

1 July 2004

evaluating a GPI-0100 and folate antigen complex for renal cancer. A Phase I/II trial at the prestigious Memorial Sloan-Kettering Cancer Center in New York was conducted in 2003 to evaluate a GP1-0100/antigen complex to prevent recurrence of prostate cancer in patients that have responded to the initial treatment. Galenica also intends to commence a Phase I clinical trial using a CEA vaccine for colorectal cancer, at the UAB Comprehensive Cancer Center in 2005.

An immune enhancer or adjuvant is a critical vaccine component that is required to stimulate a protective or therapeutically effective immune response against cancer cells or infectious agents. Galenica's GPI-0100 series are safe semi-synthetic derivatives from certain natural saponins which have the capability of stimulating Th 1 immunity with production of antigen-specific cytotoxic T cells (CTL) that will seek out and destroy cells carrying abnormal markers such as viral or tumor antigens. Pre-clinical work has shown that the GPI-0100 derivatives can also be used as stand-alone drugs in cancer immunotherapy.

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**For further information on AustCancer visit [www.austcancer.com.au](http://www.austcancer.com.au).**



## **Philip Livingston, M.D. Joins AustCancer Advisory Board**

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Cancer focused bio-pharmaceutical company, Australian Cancer Technology ("AustCancer" – ASX:ACU), is pleased to announce that prominent United States cancer expert Professor Philip Livingston has accepted the company's invitation to join its Scientific Advisory Board.

Professor Livingston is a Member at Memorial Sloan-Kettering Cancer Center (MSKCC), one the country's top facilities for cancer research and treatment, and Professor of Medicine at Cornell University's Weill Medical College. He has co-authored 96 peer reviewed papers in a career spanning 35 years since graduating from Princeton and Harvard. He also sits on several government committees and the editorial boards of three specialist oncology publications.

AustCancer managing director Paul Hopper welcomed Professor Livingston's appointment. "It's clearly a major boost to AustCancer to have someone of Philip Livingston's experience and intellectual capability helping us with our scientific decision making. Being able to attract someone of his standing is also a very positive sign that AustCancer is gaining increased recognition in the international oncology community," he said.

Professor Philip Livingston joins immunologist and cancer researcher Professor Rick Phipps, neurobiologist Professor Kerry O'Banion, neuroscientist Professor David Felten and oncologist Professor Barry Boyd on the AustCancer Scientific Advisory Board, which is led by AustCancer executive chairman Dr Roger Aston.

Consistent with its strategy of expanding its portfolio of developmental cancer therapeutics, AustCancer will have increased the number of clinical trials its products are involved in from one to three after the Galenica acquisition. The Scientific Advisory Board will be involved in both overseeing the clinical trials of current products and with the evaluation of new candidate drugs emerging through the company's growing international connections, particularly in the United States.

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### **Please direct enquiries to:**

Paul Hopper  
Managing Director  
Australian Cancer Technology  
Phone: +61 2 9252 6899  
Mob: +61 407 118 366  
Email: paulhopper@austcancer.com.au

Mike Feehan  
Monsoon Communications  
Phone: +61 3 9620 3333  
Mob: +61 412 537 533

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AustCancer has completed a Level 1 ADR program on NASDAQ (AUCJY).

For further information on AustCancer visit [www.austcancer.com.au](http://www.austcancer.com.au)

ASX RELEASE  
6 July 2004**Big US Pharmacy Group to Distribute AustCancer's  
revisys™**

Australian Cancer Technology Limited ("AustCancer") (ASX: ACU) today announced that its US subsidiary, ACT (USA), has signed a distribution deal with Rochester Drug Cooperative, which will see the **revisys™** range of nutritional supplements stocked in hundreds of pharmacies in the country's northeast. Rochester Drug Cooperative is an independently owned wholesale drug cooperative, servicing more than 800 community retail pharmacies, long-term care pharmacies and home health care stores in New York State, Pennsylvania and New Jersey.

The strategic objective for **revisys™** is to become the leading choice of medical professionals for scientifically credible, high quality nutritional supplements. ACT (USA) has forged a number of significant distribution arrangements for the **revisys™** products since their release earlier this year. These include a national agreement with Strong Value, a leading supplier of premium products and services to healthcare organisations, a recent deal with Derma Spa, one of the region's only medically supervised day spas and agreements with numerous pharmacies across New York State and Connecticut.

**revisys™** is an integrated, multi-level nutrient system that provides support for four levels of health and nutritional needs, from general well being to condition-specific supplementation. It is particularly designed for patients facing unique nutritional requirements due to extenuating health issues, but it is also beneficial to individuals concerned with optimal nutritional protection and maintenance of good health.

AustCancer managing director Paul Hopper said, "We are delighted with the progress our US business is making with **revisys™**. We are ahead of our sales targets to date and the appointment of another strong distributor in Rochester Drug Cooperative gives us an excellent base on which to quickly grow the business."

The **revisys™** business is expected to be cash flow positive by the end of its first 12 months of operation with projected sales of US\$8-10 million pa in its third year.

ENDS

**PLEASE DIRECT ENQUIRIES TO:**

Paul Hopper  
Managing Director  
Australian Cancer Technology  
Tel: +61 2 9252 6899  
Fax: + 61 2 9252 6877  
Cell: +61 407 118 366  
[paulhopper@austcancer.com.au](mailto:paulhopper@austcancer.com.au)

Dr Mary Maida  
CEO  
ACT (USA), INC.  
Phone +1 585-419-9710  
Fax: +1 585-419-9715

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**[www.austcancer.com.au](http://www.austcancer.com.au)**  
**[www.revisyshealth.com](http://www.revisyshealth.com)**

ASX/MEDIA RELEASE

13 July 2004

## **Pentrys™ Phase II Cancer Trial Update**

The Phase II clinical trial of Australian Cancer Technology's ("AustCancer") (ASX:ACU) Pentrys™ anti-idiotypic cancer vaccine is progressing well with 19 prostate cancer patients now enrolled.

The study, which commenced on April 28, is evaluating a new vaccine for men with hormone refractory prostate cancer and is being conducted by Cancer Trials Australia at three sites in Melbourne: Austin Hospital, Royal Melbourne Hospital and Peter MacCallum Cancer Centre. It is planned that a total of 40 patients will be enrolled in the trial.

-ENDS-

### **PLEASE DIRECT ENQUIRIES TO:**

Paul Hopper  
Managing Director  
Australian Cancer Technology Ltd  
Phone: +61-2 9252 6899  
Mob: +61-407 118 366

Assoc. Prof Mark Rosenthal (Trial-related queries)  
Clinical Trials Australia  
Phone: +61 3 9342 7560

Mike Feehan  
Monsoon Communications  
Phone: +61 3 9620 3333

### **About Pentrys™**

Pentrys™ works by inducing the production of a cascade of antibodies, which trigger an immune response against tumour cells with a mutated p53 gene. Mutated p53 occurs in up to 50% of all cancer patients. Therefore, Pentrys™ differs from other vaccines currently in development in that it can be used in up to 50% of all cancer patients and across a broad spectrum of cancer types. Most other development vaccines are designed to treat one specific type, or sub-type, of cancer and many use a patient's own cells and are therefore individually tailored for each patient resulting in regulatory as well as cost and time efficiency issues. Pentrys™ has no such issues making it a potential blockbuster product of interest to global pharmaceutical companies when compared to most competing technologies. The potential market for the vaccine has been estimated at US\$2 billion per annum.

### **About Australian Cancer Technology**

Australian Cancer Technology is a broadly based international oncology company developing a portfolio of high quality oncology-related projects that are at various stages of commercialisation. Cash generating businesses will provide the funds to exploit the potential of its leading products and to introduce promising pre-clinical and Phase I projects into the development pipeline. Its leading edge Pentrys™ anti-cancer vaccine successfully completed Phase I and Phase I/IIa trials at St. Vincent's Hospital Sydney and is undergoing a comprehensive Phase IIb trial with prostate cancer patients at three leading Melbourne institutions. Its US subsidiary, *revisys*™, is launching a range of nutritional supplements designed by leading US scientists for people with special needs, including those undergoing cancer treatment. The company is also broadening its cancer therapeutic development pipeline and has recently announced the acquisition of US based Galenica Pharmaceuticals, whose immune enhancing products are being used in three Phase I and II cancer trials and will be used in a number of other forthcoming clinical trials in association with Memorial Sloan Kettering Cancer Centre in New York. AustCancer has established a Level 1 ADR program in the US, trading under the code of AUCJY.